

# **HERMES DECLARATION EXHIBIT 15 – PART 1 OF 8**

1W 1270368

# THE UNITED STATES OF AMERICA

**TO ALL TO WHOM THESE PRESENTS SHALL COME:**

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office

February 04, 2005

THIS IS TO CERTIFY THAT ANNEXED IS A TRUE COPY FROM THE  
RECORDS OF THIS OFFICE OF THE FILE WRAPPER AND CONTENTS  
OF:

APPLICATION NUMBER: 07/838,511

FILING DATE: February 19, 1992

PATENT NUMBER: 5,314,446

ISSUE DATE: May 24, 1994



By Authority of the  
COMMISSIONER OF PATENTS AND TRADEMARKS

*N. Woodson*  
N. WOODSON

Certifying Officer

PART ( ) OF PART(S)

7 838511		PATENT DATE MAY 24 1992		PATENT NUMBER 5314446	
SERIAL NUMBER 07/838,511	FILING DATE 02/19/92	CLASS 606	SUBCLASS	GROUPART U 1504	5314446

ALASTAIR W. HUNTER, BRIDGEWATER, NJ; ARTHUR TAYLOR JR., PLAINFIELD, NJ;  
MARK STECKEL, MAINEVILLE, OH.

\*\*CONTINUING DATA\*\*\*\*\*  
VERIFIED

\*\*FOREIGN/PCT APPLICATIONS\*\*\*\*\*  
VERIFIED

FOREIGN FILING LICENSE GRANTED 03/05/92

Foreign priority claimed USC 119 conditions met	<input type="checkbox"/> yes <input type="checkbox"/> no	AS FILED	STATE OR COUNTRY NJ	SHEETS DRWGS. 3	TOTAL CLAIMS 24	INDEP. CLAIMS 1	FILING FEE RECEIVED \$770.00	ATTORNEY'S DOCKET NO. ETH-782
--	--	----------	------------------------	-----------------------	-----------------------	-----------------------	------------------------------------	-------------------------------------


ROBERT L. MINIER  
ONE JOHNSON & JOHNSON PLAZA  
NEW BRUNSWICK, NJ 08933-7003

STERILIZED HETEROGENEOUS BRAIDS

U.S. DEPT. of COMM.-Pat. & TM Office - PTO-436L (rev. 10-78)

PTS OF APPLICATION  
ED SEPARATELY

DATE OF ALLOWANCE MAILED 11-18-93		PREPARED FOR ISSUE CHRIS RAYMOND Assistant Examiner		CLAIMS ALLOWED Total Claims 12	
ISSUE FEE Amt Due 70.00		DATE PAID 2-18-94		DRAWING Sheets 3	
Label Area		ISSUE CLASSIFICATION Class 606		ISSUE BATCH NUMBER 567	
<p>WARNING: The information disclosed herein may be restricted. Unauthorized disclosure prohibited by the United States Code Title 35, Sections 122, 181 and 368. Possession outside the U.S. Patent &amp; Trademark Office is restricted to authorized and contractors only.</p>					

		U.S. PATENT APPLICATION			
SERIAL NUMBER		FILING DATE	CLASS	GROUP ART UNIT	
07/838,511		02/19/92	264	1304	
APPLICANT	ALASTAIR W. HUNTER, BRIDGEWATER, NJ; DENNIS D. JAMIOLKOWSKI, LONG VALLEY, NJ; ARTHUR TAYLOR JR., PLAINFIELD, NJ; MARK STECKEL, MAINEVILLE, OH.				
	**CONTINUING DATA***** VERIFIED				
	**FOREIGN/PCT APPLICATIONS***** VERIFIED				
FOREIGN FILING LICENSE GRANTED 03/05/92					
STATE OR COUNTRY	SHEETS DRAWING	TOTAL CLAIMS	INDEPENDENT CLAIMS	FILING FEE RECEIVED	ATTORNEY DOCKET NO.
NJ	3	24	1	\$ 770.00	ETH-782
ADDRESS	ROBERT L. MINIER ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003				
TITLE	STERILIZED HETEROGENEOUS BRAIDS				
This is to certify that annexed hereto is a true copy from the records of the United States Patent and Trademark Office of the application as filed which is identified above.  By authority of the COMMISSIONER OF PATENTS AND TRADEMARKS					
Date		Certifying Officer			

838511

PATENT APPLICATION SERIAL NO. \_\_\_\_\_

U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE  
FEE RECORD SHEET

DF11186 02/28/92 07838511 10-0750 110 101 770.00CH ETH-782

PTO-1556  
(5/87)

DePuy Mitek, Inc. v. Arthrex, Inc.  
C.A. No.04-12457 PBS  
**DMI000013**

Case Docket No.: ETH-782

THE COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

Sir:

Transmitted herewith for filing is the patent application of

Inventor: Alastair Hunter et al.

For : STERILIZED HETEROGENEOUS BRAIDS

Enclosed are:

- ☒ Three (3) sheets of drawings (Formal).
- ☒ Two signed Declarations and Powers of Attorney.
- ☒ Two assignments of the invention to Ethicon, Inc.
- ☐ A certified copy of a \_\_\_\_\_ application.
- ☐ Associate Power of Attorney.
- ☒ Information Disclosure Statement.
- ☒ One stamped, self-addressed postcard for the PTO Mail Room date stamp.

## CLAIMS AS FILED

(1)	(2)	(3)	(4)	(5)
FOR:	NUMBER FILED	NUMBER EXTRA	RATE	BASIC FEE \$690.00
TOTAL CLAIMS	24 - 20 =	4	x 20.00	\$ 80.00
INDEPENDENT CLAIMS	1 - 3 =	0	x 72.00	\$ 000.00
MULTIPLE DEPENDENT CLAIMS	no		\$220.00	\$ 000.00

TOTAL FILING FEE \$ 770.00

<input checked="" type="checkbox"/>	FEE FOR RECORDING ASSIGNMENT	\$40.00	\$ 40.00
-------------------------------------	------------------------------	---------	----------

TOTAL FEES \$ 810.00

- ☒ Please charge Deposit Account No. 10-750/ETH-782/MSG in the amount of \$810.00. Three copies of this sheet are enclosed.
- ☒ The Commissioner is hereby authorized to charge any additional fees which may be required in connection with the filing of this communication, or credit any overpayment, to Account No. 10-750/ETH-782/MSG. Three copies of this sheet are enclosed.
- ☐ A check in the amount of \$\_\_\_\_\_ to cover the total fee is enclosed.
- ☒ Address all correspondence to Robert L. Minier, One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933-7003.

*Matthew S. Goodwin*  
Attorney of Record  
Reg. No. 32,839

Matthew S. Goodwin  
Johnson & Johnson  
One Johnson & Johnson Plaza  
New Brunswick, NJ 08933-7003  
(908) 524-2791  
February 19, 1992

VIA EXPRESS MAIL NO. HB346860113  
MAILED FEBRUARY 19, 1992



DOCKET NO. ETH-782

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Alastair Hunter et al.  
For : STERILIZED HETEROGENEOUS BRAIDS

Express Mail Certificate

"Express Mail" mailing number HB346860118

Date of Deposit February 19, 1992

I hereby certify that this complete application, including specification pages, claims, formal drawings, Information Disclosure Statement, PTO-Form 1449, Assignments, and Declarations and Powers of Attorney, is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner of Patent and Trademarks, Washington, D.C. 20231.

Matthew S. Goodwin

(Typed or printed name of person mailing paper or fee)

*Matthew Goodwin*

(Signature of person mailing paper or fee)

DePuy Mitek, Inc. v. Arthrex, Inc.  
C.A. No.04-12457 PBS

**DMI000015**



~~XXXXXXXXXX~~  
# 838511

- 1 -

TITLE OF THE INVENTION

STERILIZED HETEROGENEOUS BRAIDS

5 BACKGROUND OF THE INVENTION

10 This invention relates to braided multifilaments, and especially to sterilized, braided multifilaments suitably adapted for use as surgical sutures or ligatures.

15 Braided multifilaments often offer a combination of enhanced pliability, knot security and tensile strength when compared to their monofilament counterparts. The enhanced pliability of a braided multifilament is a direct consequence of the lower resistance to bending of a bundle of very fine filaments relative to one large diameter monofilament. However, for this enhancement to be realized, the individual multifilaments must be able to bend unencumbered or unrestricted by their neighboring filaments. Any mechanism which reduces this individual fiber mobility, such as simple fiber-fiber friction, a coating which penetrates into the braid interstices, or a melted polymer matrix which adheres fibers together, will adversely affect braid pliability. In the extreme case where the multifilaments are entirely bonded together, the pliability or bending resistance closely approximates that of a monofilament.

20 Unfortunately, the prior art abounds with attempts to improve specific properties of multifilament braids at the expense of restricting the movement of adjacent filaments which make up the braid,. For example, multifilament sutures almost universally possess a surface coating to improve handling properties.

ETH-782

2

VIA EXPRESS MAIL NO. HB346860118  
MAILED FEBRUARY 19, 1992

DePuy Mitek, Inc. v. Arthrex, Inc.  
C.A. No.04-12457 PBS  
DMI000016



- 2 -

FFB  
B  
FB

5 U.S. Patent 3,942,532 discloses a polyester coating for multifilament sutures. The preferred polyester coating is polybutylate, which is the condensation product of 1,4-butanediol and adipic acid. U.S. Patent 4,624,256 discloses a suture coating copolymer of at least 90 percent  $\epsilon$ -caprolactone and a biodegradable monomer, and optionally a lubricating agent. Examples of monomers for biodegradable polymers disclosed include glycolic acid and glycolide, as well as other well known monomers typically used to prepare bioabsorbable coatings for multifilament sutures.

FB 15

20 An alternative to the use of the commonly accepted coating compositions for multifilament sutures to improve handling properties is disclosed in U.S. Patent 3,527,650. This patent discloses a coating composition of polytetrafluoroethylene (PTFE) particles in an acrylic latex. Although the PTFE particles act as an excellent lubricant to decrease the surface roughness of multifilament sutures, the particles have a tendency to flake off during use. Also, this particular coating is a thermoset which requires a curing step for proper application.

FB

25 More recently, a dramatic attempt has been made to create a monofilament-like surface for a multifilament suture. U.S. Patent 4,470,941 discloses the preparation of "composite" sutures derived from different synthetic polymers. The composite suture is composed of a core of low melting fibers around which are braided high melting fibers. Because of the lack of cohesiveness of the dissimilar fibers, the low melting fibers in the core are melted and redistributed throughout the matrix of the braided, high melting fibers. Although these composite

ETH-782

3

- 3 -

sutures represent an attempt to combine the best properties of different synthetic fibers, it unfortunately fails in this respect due to increased stiffness (as evidenced by Figure 3 which is described in detail below),  
5 apparently due to the reduction of fiber mobility resulting from the fusing of the fibers together.

Another attempt to enhance the properties of multifilament sutures can be found in WO 86/00020. This application  
10 discloses coating an elongated core of a synthetic polymer having a knot tenacity of at least 7 grams/denier with a film-forming surgical material. The film-forming surgical material can be absorbable or nonabsorbable, and can be  
15 coated on the elongated core by solution casting, melt coating or extrusion coating. Such coated multifilament sutures suffer from the same deficiencies which plague conventionally coated multifilament sutures.

All of the attempts described in the prior art to improve braid properties have overlooked the importance of fiber-fiber friction and its impact on fiber mobility and braid pliability. The properties of concern here include the fiber-fiber frictional coefficients (which frequently relate to the polymer's surface energy), the fiber cross-sectional shape and diameter, and the braid structure which influences the transverse forces across the braid. If fibers composed of highly lubricous polymers are used in the traditional manner, then a highly pliable braid can be prepared. However, in most cases, these braids will be  
30 relatively weak and unusable. Hence, a tradeoff between braid strength and pliability exists in the design of conventional braided multifilaments.

ETH-782

- 4 -

In view of the deficiencies of the prior art, it would be desirable to prepare multifilament sutures exhibiting improved pliability and handling properties. More specifically, it would be most desirable to prepare braided multifilaments composed of dissimilar fiber-forming materials in which the fiber-forming materials contribute significantly to enhanced pliability for the braided multifilament without appreciably sacrificing its physical properties.

SUMMARY OF THE INVENTION

The invention is a heterogeneous braid comprising a first and second set of continuous and discrete yarns in a sterilized, braided construction. At least one yarn from the first set is in direct intertwining contact with a yarn from the second set.

Each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material, and each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material.

Surprisingly, the heterogeneous braids may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns. The dissimilar fiber forming materials do not require melt bonding or any other special processing techniques to prepare the heterogeneous braids of this invention. Instead, the integrity of the braid and therefore its properties is due entirely to the mechanical interlocking or weaving of the individual yarns. In fact, it is possible to tailor the physical and biological properties of the braid by varying

ETH-782

- 5 -

the type and proportion of each of the dissimilar fiber forming materials used, as well as adjusting the specific configuration of the braid. For example, in preferred embodiments, the heterogeneous braid will exhibit improved  
 5 pliability and handling properties relative to that of conventional homogeneous fiber braids, without sacrificing physical strength or knot security.

The sterilized, heterogeneous braids of this invention are  
 10 useful as surgical sutures or ligatures, as well as for the preparation of any other medical device which would benefit from its outstanding physical or biological properties.

*DECL* 15 BRIEF DESCRIPTION OF THE DRAWINGS

*F*  
 Figure 1 illustrates a carrier layout for the preparation of a heterogeneous braid within the scope of this invention;

20 Figure 2 is a plot representing the relationship between the tensile strength of heterogeneous and homogeneous braids of polyethylene terephthalate (PET) and PTFE yarns, and the volume fraction of PTFE yarns in the braids; and

25 Figure 3 is a plot representing a relationship between the initial bending rigidity of heterogeneous and homogeneous braids of PET and PTFE yarns, and the volume fraction of PTFE yarns in the braids.

30 *DECL* DETAILED DESCRIPTION OF THE INVENTION

*F*  
 For purposes of describing this invention, a "heterogeneous" braid is a configuration composed of at

ETH-782  
*G*

DePuy Mitek, Inc. v. Arthrex, Inc.  
 C.A. No. 04-12457 PBS  
 DMI000020

- 6 -

least two sets of dissimilar yarns mechanically blended by  
intertwining the dissimilar yarns in a braided  
construction. The yarns are continuous and discrete, so  
therefore each yarn extends substantially along the entire  
5 length of the braid and maintains its individual integrity  
during braid preparation, processing and use.

FB  
L  
10 The heterogeneous braids of this invention can be  
conventionally braided in a tubular sheath around a core  
of longitudinally extending yarns, although such a core  
may be excluded, if desired. Braided sheath sutures with  
central cores are shown in U.S. Patent Nos. 3,187,752;  
4,043,344; and 4,047,533, for example. A core may be  
advantageous because it can provide resistance to  
15 flattening, as well as increased strength. Alternatively,  
the braids of this invention can be woven in a spiral or  
spiroid braid, or a lattice braid, as described in U.S.  
Patent Nos. 4,959,069 and 5,059,213.

FB  
20 The dissimilar yarns of the first and second set of yarns  
are braided in such a manner that at least one yarn from  
the first set is directly intertwined with, or entangled  
about, a yarn from the second set. Direct mechanical  
blending of individual, dissimilar yarns therefore occurs  
25 from the interweaving and interlocking of these dissimilar  
yarns, enhancing yarn compatibility and the overall  
physical and biological properties of the heterogeneous  
braid. Preferably, every yarn from the first set is in  
direct intertwining contact with a yarn of the second set  
30 to achieve the maximum degree of mechanical blending of  
the dissimilar yarns.

The first and second fiber-forming materials which make up  
the filaments of the first and second set of yarns,

ETH-782

7

DePuy Mitek, Inc. v. Arthrex, Inc.  
C.A. No. 04-12457 PBS  
DMI000021

- 7 -

respectively, can be any materials capable of being spun into continuous filaments. Advantageously, the fiber-forming materials are nonmetallic.

5 The preferred fiber-forming materials are synthetic fiber-forming polymers which are melt or solution spun through a spinneret to prepare continuous filaments. The filaments so prepared are advantageously stretched to provide molecular orientation and annealed to enhance  
10 dimensional stability and/or biological performance. The fiber-forming polymers can be bioabsorbable or nonabsorbable, depending on the particular application desired. Examples of monomers from which bioabsorbable polymers are derived include, but are not limited to, some  
15 hydroxyacids and lactones, e.g. glycolic acid, lactic acid, glycolide, lactide, p-dioxanone,  $\epsilon$ -caprolactone and trimethylene carbonate, as well as copolymers and polymer blends derived from these monomers and others. Interestingly, numerous bioabsorbable heterogeneous braids  
20 exhibiting varying useful biological properties, such as breaking strength retention in vivo and the absorption profiles in vivo, can be prepared for specific applications by using different combinations of bioabsorbable polymers.

25 Preferably, the continuous filaments which make up the first and second set of yarns are derived from nonabsorbable polymers. In a preferred embodiment, the first set of yarns acts as lubricating yarns to improve  
30 the overall pliability, or compliance, and surface lubricity of the heterogeneous braid. Preferably, the fiber-forming material of the first set exhibits a surface energy (which frequently relates to surface lubricity) less than about 38 dyne/cm, as measured by contact angle

ETH-782

DePuy Mitek, Inc. v. Arthrex, Inc.  
C.A. No. 04-12457 PBS  
DMI000022

- 8 -

of liquids on polymer surfaces, as described by Kissa, E., "Handbook of Fiber Science and Technology," Vol. II, Part B, Marcel Decker, 1984. Such fiber forming polymers include perfluorinated polymers, e.g. PTFE and fluorinated ethylene/propylene copolymers (FEP) and perfluoroalkoxy (PFA) polymers, as well as non-perfluorinated polymers such as polyvinylidene fluoride (PVDF), polyethylene/tetrafluoroethylene copolymers (PETFE), the polychlorofluoroethylene polymers, polypropylene (PP) and polyethylene (PE). More preferably, the first fiber-forming material exhibits a surface energy less than about 30 dyne/cm. The preferred polymers for the first set are PTFE, PETFE, FEP, PE and PP, and the most preferred fiber forming polymer is PTFE.

15

In a more preferred embodiment, the lubricating yarns of the first set are mechanically blended with yarns of the second set which act to provide improved strength to the heterogeneous braid. Preferably, the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier, more preferably greater than 5.0 grams denier. The preferred yarns are PET, nylon and aramid, and the most preferred yarns are PET.

20

In the most preferred embodiment, the heterogeneous braid is composed of a first set of PTFE yarns mechanically blended with a second set of PET yarns in a braided configuration. Advantageously, the braided sheath encloses a core of longitudinally extending PET yarns to further improve the overall strength and resistance to flattening of the heterogeneous braid. In this embodiment, the volume fraction of lubricating yarns in the braided sheath and core desirably ranges from about 20 to about 80 percent. A volume fraction of lubricating yarns below

30

ETH-782

- 9 -

about 20 percent will not typically improve the pliability of the braid, and a volume fraction above about 80 percent may adversely affect the overall strength of the braid. The filament fineness for such a heterogeneous braid is preferably less than 10 denier per filament, preferably from about 0.5 to about 5 denier per filament. A more coarse filament may result in a stiffer braid. The preferred individual yarn denier is between 10 and 100 denier.

10

The heterogeneous braids of this invention can be prepared using conventional braiding technology and equipment commonly used in the textile industry, and in the medical industry for preparing multifilament sutures. For example, the first and second set of yarns can be interwoven as indicated by the plan view of the yarn carrier layout of Figure 1 for the preparation of a braided multifilament. The individual yarns of the braided sheath feed from spools mounted on carriers 22, 22' and 24, 24'. The carriers move around the closed circular loop 28, moving alternately inside and outside the loop 28 to form the braiding pattern. One or more carriers are continually following a serpentine path in a first direction around the loop, while the remaining carriers are following a serpentine path in the other direction.

25

In the illustrated embodiment, carriers 22, 22' are travelling around serpentine path 27 in a clockwise direction as indicated by directional arrows 23, and carriers 24, 24' are travelling around serpentine path 29 in a counterclockwise direction as indicated by arrows 25. The moving carriers dispense yarns which intertwine to form the braid. The yarns from all the carriers in a constructed embodiment of Figure 1 are dispensed upward

ETH-782

10



- 10 -

with respect to the plane of the drawing, and the braid is taken up on a reel located above the plane of the drawing.

In one embodiment, moving carriers 22, 24 dispense yarns of the first set and moving carriers 22', 24' dispense yarns of the second set to form the heterogeneous braid.

In a more preferred embodiment, moving carriers 22, 22' dispense yarns of the first set and moving carriers 24, 24' dispense yarns of the second set. This carrier layout provides a braid in which each yarn of the first set is directly intertwined with a yarn from the second set.

Advantageously, as illustrated in Figure 1, disposed within the center of the loop 28 are carriers 26 which dispense the core yarns of the braid. In the most preferred embodiment of this invention, moving carriers 22, 22' dispense PTFE yarns, moving carriers 24, 24' dispense PET yarns, and core carriers 26 dispense PET yarns.

Numerous additional embodiments are contemplated within the scope of the invention using conventional braiding technology and equipment. For example, the carrier layout can be modified to prepare a braid configuration using from 3 to 28 sheath carriers, with or without any number of core yarns. Dissimilar yarns from the first and second set of yarns can be plied together using conventional techniques before braiding, and in this embodiment, the carriers can dispense identical bobbins of plied yarns composed of individual yarns from the first and second sets. This embodiment not only offers the advantage of inter-yarn mechanical blending, but also the intimate mixing associated with intra-yarn blending.

ETH-782

- 11 -

Similar to the preparation of conventional homogeneous braids, the yarns from which the heterogeneous braids are prepared are preferably nontextured. The yarn tension during braiding is advantageously adjusted so that the yarn elongation for each set of yarns is about equal. The equilibration of yarn elongation may prevent irregularities, for example, "core popping", which is the tendency of core yarns to break through the braided sheath as the braid is bent. The number of picks per inch in the finished braid can be adjusted to balance the tensile strength of the braid with braid quality, e.g the tendency for core popping and overall braid smoothness.

After the heterogeneous braid is prepared, it is desirably scoured to remove machine oils and lubricants, and any foreign particles. The scoured braid is preferably stretched at a temperature between the glass transition temperature and melting temperature of the lower melting set of yarns. Therefore, the stretching temperature is such that none of the yarns is actually melted. The stretching operation densifies the braid and improves braid smoothness. Afterwards, the braid may be annealed while under restraint to improve dimensional stability, and in the case of absorbable braids, to improve the breaking strength retention in vivo.

If desired, the surface of the heterogeneous multifilament braid can be coated with a bioabsorbable or nonabsorbable coating to further improve the handleability and knot tiedown performance of the braid. For example, the braid can be immersed in a solution of a desired coating polymer in an organic solvent, and then dried to remove the solvent. Most preferably, the coating does not cause the fibers or yarns to adhere to one another increasing

ETH-782

12

DePuy Mitek, Inc. v. Arthrex, Inc.  
C.A. No. 04-12457 PBS  
DMI000026

- 12 -

stiffness. However, if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricous yarn system, the conventional coating may be eliminated saving expense as well as avoiding the associated braid stiffening.

If the surface of the braid is coated, than the coating composition may desirably contain bioactive materials such as antibiotics and growth factors.

The post-treated heterogeneous braid is sterilized so it can be used for a host of medical applications, especially for use as a surgical suture, preferably attached to a needle. The braid can be sterilized using any of the conventional techniques well known in the art. For example, sterilization can be effected by exposing the braid to gamma radiation from a cobalt 60 source. Alternatively, the braid can be sterilized by exposure to ethylene oxide.

In the following examples, the tensile properties and knot security are each determined using an Instron Tensile Tester. The tensile properties, i.e. the straight and knot tensile strength and the percent elongation, are determined generally according to the procedures described in U.S. Patent 4,838,267. The knot security, which provides an indication as to the number of throws required to secure a knot so that it fails to slip before cleanly breaking, is measured by first tying a conventional square knot around a mandrel, pulling the knot apart on the Instron Tester to observe whether slipping occurs, and if so, then tying knots with additional throws until 20 out of 20 knots break cleanly without slipping. The bending rigidity, which is the inverse of pliability, is

ETH-782

- 13 -

determined using a Kawabata Pure Bending Tester, as discussed in "The Effects of Structure on the Geometric and Bending Properties of Small Diameter Braids", Drexel University Master Thesis, 1991, by Mr. E. Ritter.

5

The examples are illustrative only, and are not intended to limit the scope of the claimed invention. The types of yarns used to prepare the heterogeneous braid and the yarn geometry can be varied to prepare heterogeneous braids within the scope of the claimed invention which exhibit a combination of outstanding physical or biological properties.

10

CL

#### EXAMPLES

15

P

B

20

B<sup>F</sup>

25

Examples I and II describe heterogeneous braids of PTFE and PET yarns. In order to evaluate the relative performance of these braids, two controls are included which represent 100% PET and 100% PTFE braids, respectively. To the extent possible, the yarn materials and processing conditions are identical for the controls and heterogeneous braid examples. In addition, for comparison purposes, a braid is fabricated with identical materials but processed per the prior art U.S. Patent 4,470,941.

#### CONTROL I

CL

PB33

30

P

FIBER MATERIALS: An 8x0 PET braid is fabricated, i.e. 8 sheath yarns and 0 core yarns. All yarns are Dupont Dacron PET, 70 denier, 48 filament, type 52 yarn.

PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each

ETH-782

14

- 14 -

B  
B  
B  
5  
CL  
PB33  
P  
B  
15  
CL  
20  
PB33  
B  
25  
P  
30  
B  
B

carrier of a N.E. Butt 8 carrier braider. Machine settings include: 32 pick gear, 0.009" wire tension springs, and 183 rpm. The braid is aqueous scoured, and hot stretched at 30% draw ratio at 225 C°.

#### CONTROL II

FIBER MATERIALS: An 8x0 PTFE braid is fabricated. All yarns are Dupont Teflon, 110 denier, 12 filament.

PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 36 pick gear, no tension springs, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

#### EXAMPLE I

FIBER MATERIALS: An 8x0 heterogeneous braid is fabricated, consisting of four PET 70 denier yarns and four PTFE 110 denier yarns. The yarns are identical to that employed in CONTROL I and II. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PROCESSING: Four bobbins of PET yarn and four bobbins of PTFE yarn were wound by conventional means. The PET bobbins were loaded on the clockwise moving carriers of the N.E. Butt 8 carrier braider, and the PTFE yarn bobbins on the counter-clockwise moving carriers. Machine settings include: 32 pick gear, 0.009" tension springs on PET carriers, no springs on PTFE carriers, and 183 rpm.

ETH-782

15

- 15 -

The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE II

FIBER MATERIALS: Identical to EXAMPLE I, except that 6 PET yarns and 2 PTFE yarns were used. On a volume basis, the braid is 75.5% PET, and 24.5% PTFE.

PROCESSING: Identical to EXAMPLE I, except that 2 PET bobbins replace 2 PTFE bobbins. All other braider machine settings, scour and hot-stretch conditions are identical to CONTROL I and II and EXAMPLE I.

PRIOR ART I

FIBER MATERIALS: Identical to EXAMPLE I. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PROCESSING: Identical to EXAMPLE I, except that the hot stretch temperature is at 300 C° and for a longer residence time to facilitate melting of the PET fibers.

ETH-782

- 16 -

The properties of CONTROLS I and II, and EXAMPLES I and II, and the PRIOR ART I are summarized in the following Table:

	USP DIAMETER (mils)	TENSILE STRENGTH (lbs)	KNOT STRENGTH (lbs)	BENDING RIGIDITY (gmXcm <sup>2</sup> )	KNOT STABILITY (# of throws)
CONTROL I	10.68	4.98	3.14	0.0680	4
CONTROL II	9.11	2.58	2.04	0.0196	7
EXAMPLE I	9.71	3.55	2.41	0.0257	5
EXAMPLE II	10.35	4.10	2.67	0.0371	5
PRIOR ART I	8.87			0.0966	

As may be expected, the tensile strengths of the heterogenous braid examples reflect the relative contributions of the individual components. This behavior is said to follow the "rule of mixtures", i.e. the composite property is a weighted average of the component properties. In equation form,

$$P_c = (Vf_a) (P_a) + (Vf_b) (P_b)$$

where  $P_c$  is a composite property (such as tensile strength or modulus),  $P_a$  and  $P_b$  are the properties of the components a and b, and  $Vf_a$  and  $Vf_b$  are the volume fractions of components a and b. This behavior is clearly observed in Figure 2, which shows a plot of tensile strength versus

ETH-782

DePuy Mitek, Inc. v. Arthrex, Inc.  
C.A. No. 04-12457 PBS

DMI000031

- 17 -

volume fraction of PTFE yarns for the Examples and Controls, in relation to the expected plot according to the rule of mixtures.

5 Surprisingly, the bending rigidity of the heterogeneous braids in EXAMPLES I and II do not follow the rule of mixtures, and show an enhanced bending rigidity relative to the weighted average of its components. This is shown in Figure 3 as a plot of bending rigidity versus %PTFE in  
10 the braids. Bending rigidity is the inverse of pliability, and is obtained by measuring the slope of the bending moment-radius of curvature plot of a suture strand in pure bending. Hence lower bending rigidity relates to a more pliable suture, which is a highly desirable  
15 property. The mechanism of this enhanced pliability is believed to be internal lubrication of the braid by the "solid lubricant" behavior of the low surface energy PTFE.

FB  
20 U.S. Patent 4,470,941 discloses the preparation of a "composite" suture with a monofilament-like surface made from multifilament yarns. The composite suture is composed of two different synthetic polymer fibers, which is thermally processed to melt one of the fibers to form a continuous matrix. This process was utilized to produce  
25 the PRIOR ART I example, the data of which is shown in Table 1 and Figure 3. It is observed that the melting of the PET fibers significantly increases the braid bending rigidity due to the bonding of the "non-melted" fibers together, hence resulting in a less pliable braid of  
30 diminished utility.

ETH-782

DePuy Mitek, Inc. v. Arthrex, Inc.  
C.A. No. 04-12457 PBS  
DMI000032



- 18 -

WHAT IS CLAIMED IS:

1. A heterogeneous braid comprising a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and:
  - a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material, and
  - b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material.
2. The heterogeneous braid of claim 1 wherein the first and second fiber-forming materials are nonmetallic.
3. The heterogeneous braid of claim 2 wherein the first and second fiber-forming materials are synthetic fiber-forming polymers.
4. The heterogeneous braid of claim 3 wherein the synthetic fiber-forming polymers are bioabsorbable.
5. The heterogeneous braid of claim 4 wherein the bioabsorbable polymers are derived from a monomer selected from the group consisting of glycolic acid, glycolide, lactide, p-dioxanone, ε-caprolactone, trimethylene carbonate, and mixtures thereof.
6. The heterogeneous braid of claim 3 wherein the fiber-forming polymers are nonabsorbable.

ETH-782

- 19 -

3. <sup>Surgical suture</sup> ~~The heterogeneous braid~~ of claim <sup>1</sup> ~~6~~ wherein the first fiber-forming material exhibits a surface energy less than about 38 dynes/cm.

5. <sup>4</sup> ~~The heterogeneous braid~~ of claim <sup>3</sup> ~~7~~ wherein the first fiber-forming material exhibits a surface energy less than about 30 dynes/cm.

9. The heterogeneous braid of claim 8 wherein the first set of yarns is PTFE, FEP, PFA, PVDF, PETFE, PP or PE.

5. <sup>Surgical suture</sup> ~~The heterogeneous braid~~ of claim <sup>1</sup> ~~9~~ wherein the first set of yarns is PTFE.

15. <sup>6</sup> ~~The heterogeneous braid~~ of claim <sup>5</sup> ~~10~~ wherein the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier.

20. <sup>7</sup> ~~The heterogeneous braid~~ of claim <sup>6</sup> ~~11~~ wherein the second set of yarns exhibits a yarn tenacity greater than 5.0 grams/denier.

25. <sup>8</sup> ~~The heterogeneous braid~~ of claim <sup>6</sup> ~~12~~ wherein the second set of yarns is PET, nylon or aramid.

<sup>8</sup> ~~The heterogeneous braid~~ of claim <sup>1</sup> ~~13~~ wherein the second set of yarns is PET.

30. <sup>15</sup> ~~The heterogeneous braid~~ of claim <sup>15</sup> ~~14~~ wherein each yarn from the first set is in direct intertwining contact with a yarn from the second set.

16. The heterogeneous braid of claim 15 wherein the braid encloses a core of longitudinally extending yarns.

ETH-782

22

DePuy Mitek, Inc. v. Arthrex, Inc.

C.A. No. 04-12457 PBS

DMI000034

- 20 -

17. The heterogeneous braid of claim 16 wherein the longitudinally extending yarns are PET.

9 surgical suture 8  
14  
5 18. The heterogeneous braid of claim 17 wherein the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent.

10 surgical suture 9  
10 19. The heterogeneous braid of claim 18 wherein the fiber fineness of the yarns of the first and second sets is less than 10 denier per filament.

11 surgical suture 1  
20. The heterogeneous braid of claim 19 wherein at least one yarn from the first set of yarns is plied together to a yarn from the second set of yarns.

21. A surgical suture comprising the heterogeneous braid of claim 1.

20 22. A surgical suture comprising the heterogeneous braid of claim 19.

2 23. The surgical suture of claim 21 wherein the suture is attached to a needle.

25 12 8 14  
24. The surgical suture of claim 22 wherein the suture is attached to a needle.

30

ETH-782

23



07/838,511

- 21 -

ABSTRACT

SA

5

Heterogeneous braided multifilament of first and second set of yarns mechanically blended by braiding, in which first and second set of yarns are composed of different fiber-forming materials.

PA

10

Heterogeneous braids are useful for preparation of surgical sutures and ligatures.

EA

15

20

25

30

ETH-782

44-38861-1000

DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

## STERILIZED HETEROGENEOUS BRAIDS,

the specification of which

(check one)      ☒      is attached hereto.

[ ] was filed on as

Application Serial No.

and was amended on \_\_\_\_\_  
(if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed: NONE

VIA EXPRESS MAIL NO. HB346860118  
MAILED FEBRUARY 19, 1992

DePuy Mitek, Inc. v. Arthrex, Inc.  
C.A. No.04-12457 PBS  
**DMI000037**

- 2 -

Prior Foreign Application(s):

Country	Application Number	Date of Filing	Priority Claimed Under 35 U.S.C. 119
		Day/Mo./Year	<input type="checkbox"/> YES <input type="checkbox"/> NO
		Day/Mo./Year	<input type="checkbox"/> YES <input type="checkbox"/> NO
		Day/Mo./Year	<input type="checkbox"/> YES <input type="checkbox"/> NO

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

Application Serial No.

Filing Date

Status (patented, pending, abandoned)

Application Serial No.

Filing Date

Status (patented, pending, abandoned)

5 I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith as well as to file equivalent patent applications in countries foreign to the United States including the filing of international patent applications in accordance with the Patent Cooperation Treaty: Robert L. Minier (Reg. #20,083), Audley A. Ciamporero, Jr. (Reg. #26,051), Steven P. Berman (Reg. #24,772), Jason Lipow (Reg. #25,509), and Matthew S. Goodwin (Reg. #32,839), One Johnson & Johnson Plaza, New Brunswick, NJ 08933.

Address all telephone calls to Matthew S. Goodwin at telephone no. (908) 524-2791.

- 3 -

Address all correspondence to, Robert L. Minier, One Johnson & Johnson Plaza, New Brunswick, NJ 08933-7003.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

1 Inventor's Signature:  
Full Name of Sole  
or First Inventor

Alastair W. Hunter  
Alastair W. Hunter

Date: 2/18/92

Citizenship: U.S.A.  
Residence: 516 Spring Valley Drive, Bridgewater, New Jersey NJ  
08807  
Post Office Address: Same as above

2 Inventor's Signature:  
Full Name of Second Joint  
Inventor, If Any

Dennis D. Jamiolkowski  
Dennis D. Jamiolkowski

Date: 2/18/92

Citizenship: U.S.A.  
Residence: 20 Fawnridge Drive, Long Valley, New Jersey 07853 NJ  
Post Office Address: Same as above

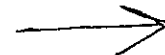
3 Inventor's Signature:  
Full Name of Third Joint  
Inventor, If Any

Arthur Taylor, Jr.  
Arthur Taylor, Jr.

Date: 2/18/92

Citizenship: U.S.A.  
Residence: 1217 East Second Street, Plainfield, New Jersey NJ  
07062  
Post Office Address: Same as above

(Supply similar information and signature for fourth and subsequent joint inventors.)



DePuy Mitek, Inc. v. Arthrex, Inc.

C.A. No.04-12457 PBS

DMI000039



TO:  
lev. 1

*DePuy Mitek, Inc. v. Arthrex, Inc.*  
C.A. No.04-12457 PBS  
**DMI000040**



**[REDACTED]**

As a below named inventor, I hereby declare that:

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

## STERILIZED HETEROGENEOUS BRAIDS,

the specification of which

[illegible]

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed: NONE

VIA EXPRESS MAIL NO. HB346860118  
MAILED FEBRUARY 19, 1992

DePuy Mitek, Inc. v. Arthrex, Inc.  
C.A. No.04-12457 PBS  
**DMI000041**

- 2 -

Prior Foreign Application(s):

Country	Application Number	Date of Filing	Priority Claimed Under 35 U.S.C. 119
		Day/Mo./Year	<input type="checkbox"/> YES <input type="checkbox"/> NO
		Day/Mo./Year	<input type="checkbox"/> YES <input type="checkbox"/> NO
		Day/Mo./Year	<input type="checkbox"/> YES <input type="checkbox"/> NO

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

Application Serial No.

Filing Date

Status (patented,  
pending, abandoned)

Application Serial No.

Filing Date

Status (patented,  
pending, abandoned)

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith as well as to file equivalent patent applications in countries foreign to the United States including the filing of international patent applications in accordance with the Patent Cooperation Treaty: Robert L. Minier (Reg. #20,083), Audley A. Ciamporzero, Jr. (Reg. #26,051), Steven P. Berman (Reg. #24,772), Jason Lipow (Reg. #25,509), and Matthew S. Goodwin (Reg. #32,839), One Johnson & Johnson Plaza, New Brunswick, NJ 08933.


Address all telephone calls to Matthew S. Goodwin at telephone no. (908) 524-2791.

- 3 -

Address all correspondence to Robert L. Minier, One Johnson & Johnson Plaza, New Brunswick, NJ 08933-7003.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

H Inventor's Signature:  
Full Name of Sole  
or First Inventor

  
Mark Steckel

Date: 2/17/92

Citizenship: U.S.A.  
Residence: 8919 Farmdale Way, Maineville, Ohio 45039 OH  
Post Office Address: Same as above

Inventor's Signature:  
Full Name of Second Joint  
Inventor, If Any

Date: \_\_\_\_\_

Citizenship:  
Residence:  
Post Office Address:

Inventor's Signature:  
Full Name of Third Joint  
Inventor, If Any

Date: \_\_\_\_\_

Citizenship:  
Residence:  
Post Office Address:

(Supply similar information and signature for fourth and subsequent joint inventors.)

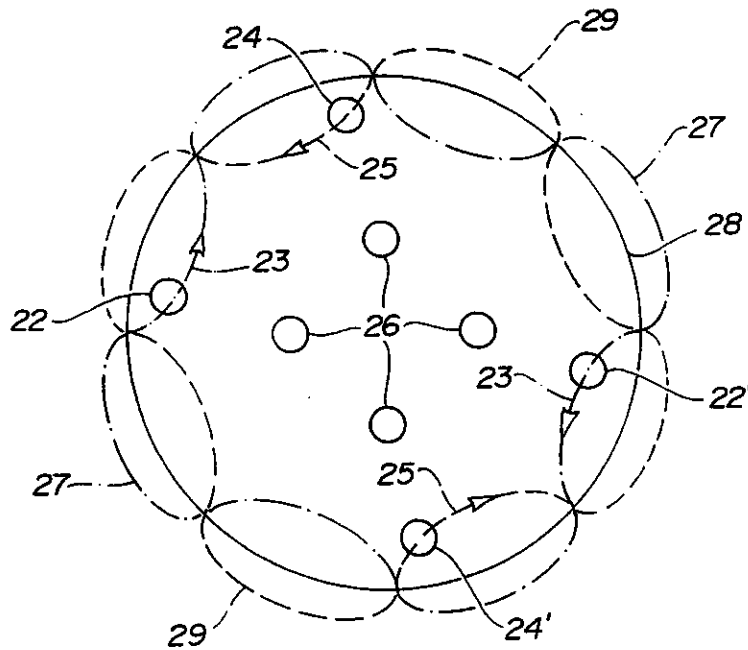


DePuy Mitek, Inc. v. Arthrex, Inc.  
C.A. No. 04-12457 PBS  
**DMI000044**

838511

5314446

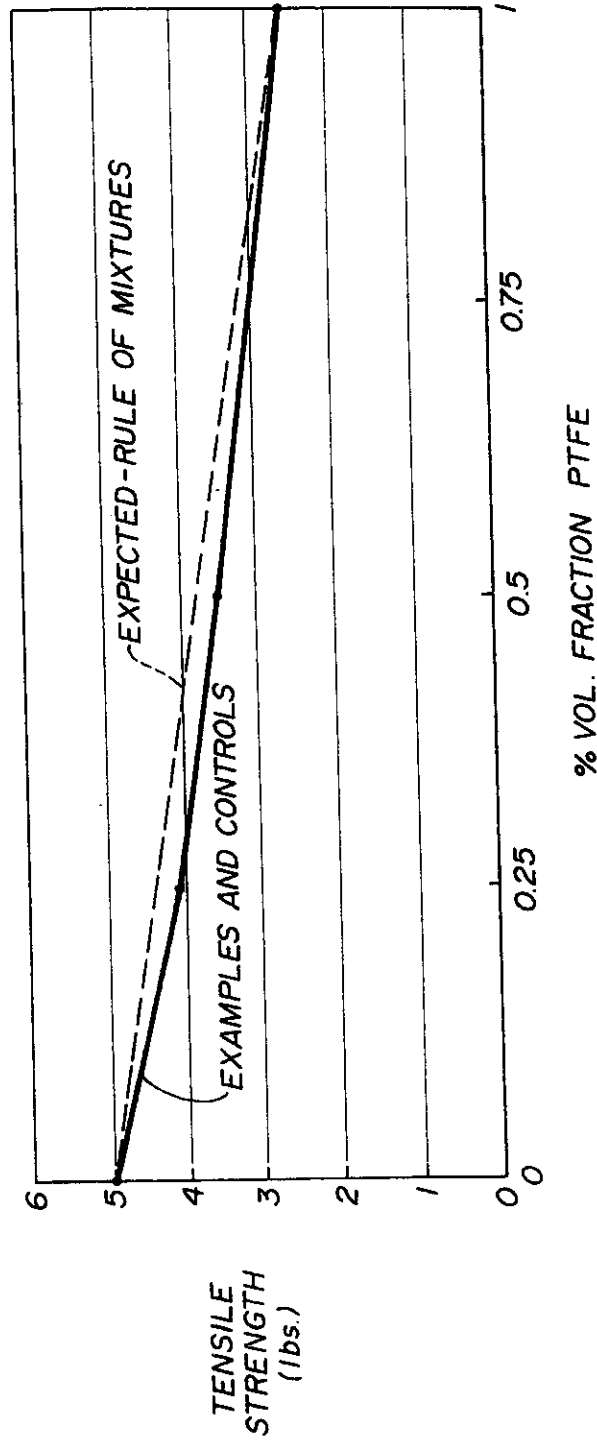
FIG-1





838511

FIG-2



017921



D-1683  
1.7-96)

DePuy Mitek, Inc. v. Arthrex, Inc.  
C.A. No.04-12457 PBS  
**DMI000048**



838511

FIG-3

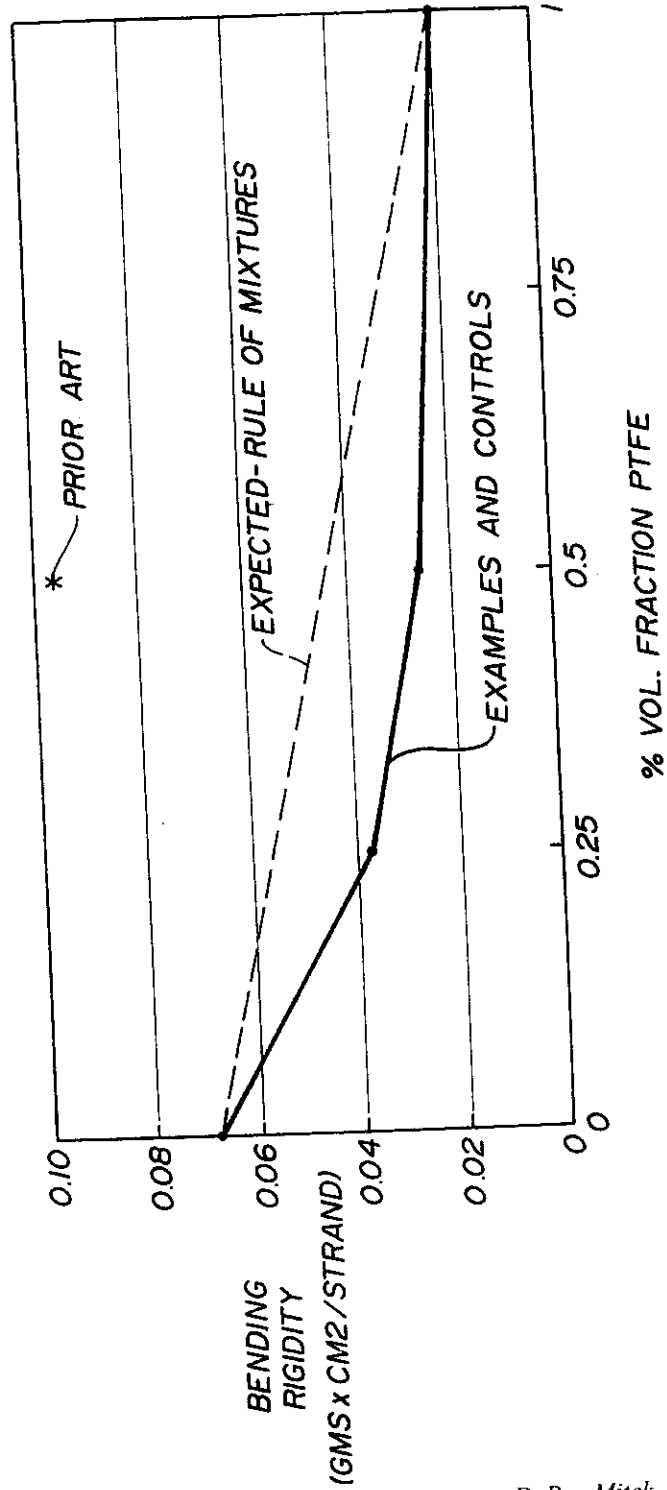




FIG-1

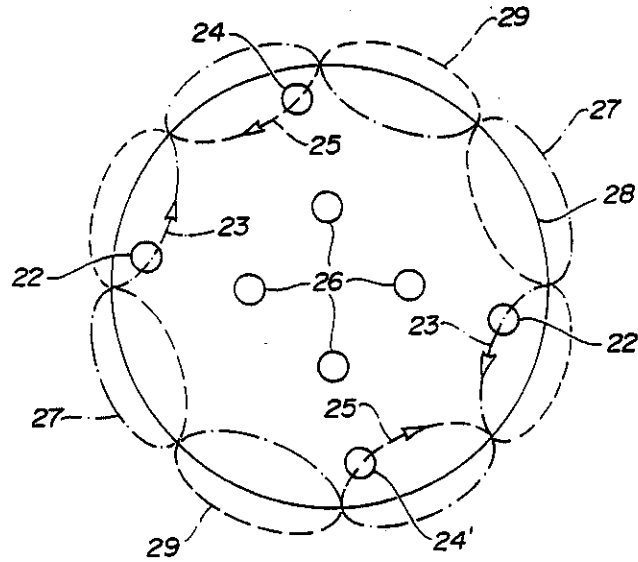


FIG-2

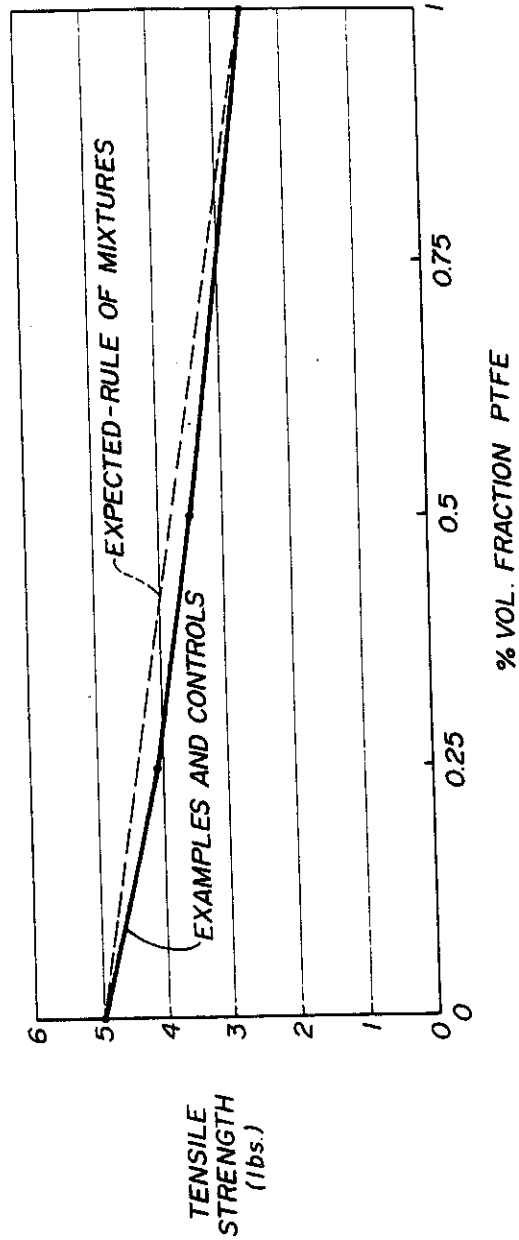


FIG-3

